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09/957,030	09/21/2001	Hideaki Yagi	Q66254	4266

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EXAMINER

RAGONESE, ANDREA M

ART UNIT PAPER NUMBER

3743

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/957,030

Applicant(s)

YAGI ET AL.

Examiner

Andrea M. Ragonese

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Amendment*

1. The Request for Continued Examiner filed on December 22, 2004 and the amendment filed on August 26, 2004 has been entered. Examiner acknowledges that **claims 1, 15 and 16** have been amended. Subsequently, **claims 1-17** are under consideration.

### *Response to Arguments*

2. Applicant's arguments with respect to **claims 1-17** have been considered but are moot in view of the new ground(s) of rejection.

### *Double Patenting*

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. **Claims 1-17** are rejected under the judicially created doctrine of double patenting over claims 1-12 of U.S. Patent No. 6,837,244 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: oxygen supply apparatus with a sensor for detecting the state of breathing of the user.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application, which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

5. **Claims 1-17** are provisionally rejected under the judicially created doctrine of double patenting over claims 1, 4-10, 12, 14-22 and 24-32 of copending Application No. 09/956,925. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant

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application are claiming common subject matter, as follows: oxygen supply apparatus with a sensor for detecting the state of breathing of the user.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

***Claim Rejections - 35 USC § 102 and 35 USC § 103***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 1-17** are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Levy et al. (US 4,340,044).

Regarding **claim 1**, Levy et al. discloses an oxygen supply apparatus which supplies oxygen or oxygen-enriched gas to a user having a breathing cycle including an inhalation period and an exhalation period synchronously with breathing of the user by means of a breath synchronization function (column 1, line 59 through column 2, line 13), as shown in Figure 1, which comprises: a sensor **62, 63** for detecting the state of breathing of the user (column 10, lines 6-9); means **1** for judging the state of breathing of the user under a predetermined judgment condition when breath-synchronized operation is performed, based on a signal from the sensor **62, 63** (column 4, line 56 through column 5, line 2); and means **1, 56** for supplying oxygen or oxygen-enriched gas to the user over a predetermined period of time when no breathing is detected (column 13, lines 12-64), based on a time period of between 0 to 40% of inspiratory

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time, as depicted in the Table in column 14. Levy et al. discloses an oxygen supply apparatus comprising all the limitations recited in **claim 1**. Although Levy et al. does not explicitly recite that the predetermined period of time is specifically in the range of 2.15 to 4.8 seconds, it would be obvious, if not inherent, given the physiological factors of respiration as recited in the Table in column 14, to use this particular time period. In addition, the Applicant has proven—see specification of the instant invention, beginning on page 6—that this time range is typical, well-known in the art and easy to derive using the same physiological factors of respiration, as set forth in the prior art of record. More specifically, Applicant states that on page 6, “the length of a breathing cycle in the case of the breathing rate being 5 to 7 times/min is 12 seconds (60 seconds/5 times) to about 8.57 seconds (60 seconds/7 times)...” Levy et al. uses a respiration rate of 6 to 40 times/min; therefore, the length of a breathing cycle in this instance would be 10 seconds (60 seconds/6 times) to about 1.2 seconds (60 seconds/40 times). Applicant further states, “...25 to 40% the length is 4.8 seconds (12 seconds x 0.4) to 2.15 seconds (about 8.57 seconds x 0.25).” Calculations for the prior art specifications would yield that the length falls in the range of 4.0 seconds (10 seconds x 0.4) to 0.3 seconds (1.2 seconds x 0.25), wherein the claimed range partially (64%) falls within the calculated range of the prior art of record. Therefore, it would be obvious, if not inherent to use this particular time period range, based on the individual's needs and physical characteristics.

Regarding **claim 2**, an oxygen supply apparatus further comprises an oxygen cylinder **16** filled with oxygen, or an oxygen enriching apparatus, which enriches oxygen contained in air (column 2, lines 29-46).

Regarding **claim 3**, wherein the predetermined judgment condition is such that a period during which the state of breathing of the user cannot be detected is a period corresponding to a breathing rate of 7 times/min or less, which falls into the range of 6 to 40 breaths/minute as disclosed by the prior art in the Table in column 14.

Regarding **claim 4**, wherein the predetermined judgment condition is such that a period during which the state of breathing of the user cannot be detected is 8 seconds or longer. Applicant states on page 5, "The breathing rate of 7 times/min is considerably slow, and in that case, the length of each breathing cycle is about 8.57 seconds (60 seconds/7 times)." Levy et al. uses a respiratory rate of 6 times/min as the lower limit of the range, corresponding to 10 seconds, which falls into the range of "8 seconds or longer."

Regarding **claim 5**, wherein the predetermined period of time is a time corresponding to 25 to 40% the length of each breathing cycle at a time when the breathing rate is 5 to 7 times/min. Levy et al. discloses an "inspiration plateau" of "0 to 40% of inspiratory time, during which time there is no flow and no patient exhalation" and an "respiratory rate" of "6 to 40 breaths/minute," which encompasses the claimed range of "25 to 40% the length of each breathing cycle at a time when the breathing rate is 5 to 7 times/min."



Regarding **claim 6**, wherein the sensor **62** is disposed at an oxygen outlet to which oxygen or oxygen-enriched gas is supplied and is adapted to detect the state of a gas at that position (column 10, lines 6-9).

Regarding **claim 7**, wherein the sensor **63** is disposed at an oxygen outlet to which oxygen or oxygen-enriched gas is supplied and is adapted to detect the state of a gas at that position (column 10, lines 6-9 and column 20, lines 13-15).

Regarding **claim 8**, wherein the sensor **62, 63** is a pressure sensor, a strain gauge sensor or a piezoelectric sensor.

Regarding **claim 9**, as disclosed throughout the entire specification, wherein the oxygen supply apparatus is an oxygen enriching apparatus; when the breath-synchronized operation is not performed, the oxygen enriching apparatus is fully capable of supplying the oxygen-enriched gas at a flow rate equal to or less than a continuous base flow rate, that is the flow rate at which the oxygen enriching apparatus can supply the oxygen-enriched gas continuously; and when the breath-synchronized operation is performed, the oxygen enriching apparatus is fully capable of supplying the oxygen-enriched gas during the inhalation period of a breathing cycle at a flow rate greater than the continuous base flow rate and stops supply of the oxygen-enriched gas during the exhalation period of the breathing cycle.

Regarding **claim 10**, as disclosed throughout the entire specification, wherein the oxygen supply apparatus is an oxygen enriching apparatus; and when the breath-synchronized operation is performed, the oxygen enriching apparatus is fully capable of supplying the oxygen-enriched gas during the inhalation period of a breathing cycle at a

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flow rate greater than a continuous base flow rate, that is the flow rate at which the oxygen enriching apparatus is fully capable of supplying the oxygen-enriched gas continuously, and supplying the oxygen-enriched gas during the exhalation period of a breathing cycle at a flow rate less than the continuous base flow rate.

Regarding **claim 11**, as disclosed throughout the entire specification, wherein when the breath-synchronized operation is not performed, the oxygen enriching apparatus is fully capable of supplying the oxygen-enriched gas at a flow rate equal to or less than a continuous base flow rate, that is the flow rate at which the oxygen enriching apparatus is fully capable of supplying the oxygen-enriched gas continuously.

Regarding **claims 12-14**, wherein the continuous base flow rate is fully capable of being 4 liters/min or less, which falls within the range of 2 to 30 liters/minute (column 14), depending on what value to which dial 6 is set.

Regarding **claim 15**, Levy et al. discloses a controller **1** for controlling the operation of an oxygen supply apparatus which supplies oxygen or oxygen-enriched gas to a user having a breathing cycle including an inhalation period and an exhalation period synchronously with breathing of the user by means of a breath synchronization function (column 1, line 59 through column 2, line 13), as shown in Figure 1, which comprises: a sensor **62, 63** for detecting the state of breathing of the user (column 10, lines 6-9); means **1** for judging the state of breathing of the user under a predetermined judgment condition when breath-synchronized operation is performed, based on a signal from the sensor **62, 63** (column 4, line 56 through column 5, line 2); and means **1, 56** for supplying oxygen or oxygen-enriched gas to the user over a predetermined

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period of time when no breathing is detected (column 13, lines 12-64), based on a time period of between 0 to 40% of inspiratory time, as depicted in the Table in column 14. Levy et al. discloses an oxygen supply apparatus comprising all the limitations recited in **claim 15**. Although Levy et al. does not explicitly recite that the predetermined period of time is specifically in the range of 2.15 to 4.8 seconds, it would be obvious, if not inherent, given the physiological factors of respiration as recited in the Table in column 14, to use this particular time period. In addition, the Applicant has proven—see specification of the instant invention, beginning on page 6—that this time range is typical, well-known in the art and easy to derive using the same physiological factors of respiration, as set forth in the prior art of record. More specifically, Applicant states that on page 6, “the length of a breathing cycle in the case of the breathing rate being 5 to 7 times/min is 12 seconds (60 seconds/5 times) to about 8.57 seconds (60 seconds/7 times)...” Levy et al. uses a respiration rate of 6 to 40 times/min; therefore, the length of a breathing cycle in this instance would be 10 seconds (60 seconds/6 times) to about 1.2 seconds (60 seconds/40 times). Applicant further states, “...25 to 40% the length is 4.8 seconds (12 seconds x 0.4) to 2.15 seconds (about 8.57 seconds x 0.25).” Calculations for the prior art specifications would yield that the length falls in the range of 4.0 seconds (10 seconds x 0.4) to 0.3 seconds (1.2 seconds x 0.25), wherein the claimed range partially (64%) falls within the calculated range of the prior art of record. Therefore, it would be obvious, if not inherent to use this particular time period range, based on the individual’s needs and physical characteristics.

Regarding **claims 16-17**, Levy et al. discloses a recording medium (column 20, lines 9-13) having recorded thereon means for executing the function of a controller 1 for controlling operation of an oxygen supply apparatus which supplies oxygen or oxygen-enriched gas to a user having a breathing cycle including an inhalation period and an exhalation period synchronously with breathing of the user by means of a breath synchronization function (column 1, line 59 through column 2, line 13), as shown in Figure 1, which comprises: a sensor **62, 63** for detecting the state of breathing of the user (column 10, lines 6-9); means 1 for judging the state of breathing of the user under a predetermined judgment condition when breath-synchronized operation is performed, based on a signal from the sensor **62, 63** (column 4, line 56 through column 5, line 2); and means **1, 56** for supplying oxygen or oxygen-enriched gas to the user over a predetermined period of time when no breathing is detected (column 13, lines 12-64), based on a time period of between 0 to 40% of inspiratory time, as depicted in the Table in column 14. Levy et al. discloses an oxygen supply apparatus comprising all the limitations recited in **claim 16**. Although Levy et al. does not explicitly recite that the predetermined period of time is specifically in the range of 2.15 to 4.8 seconds, it would be obvious, if not inherent, given the physiological factors of respiration as recited in the Table in column 14, to use this particular time period. In addition, the Applicant has proven—see specification of the instant invention, beginning on page 6—that this time range is typical, well-known in the art and easy to derive using the same physiological factors of respiration, as set forth in the prior art of record. More specifically, Applicant states that on page 6, “the length of a breathing cycle in the case of the breathing rate

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being 5 to 7 times/min is 12 seconds (60 seconds/5 times) to about 8.57 seconds (60 seconds/7 times)..." Levy et al. uses a respiration rate of 6 to 40 times/min; therefore, the length of a breathing cycle in this instance would be 10 seconds (60 seconds/6 times) to about 1.2 seconds (60 seconds/40 times). Applicant further states, "...25 to 40% the length is 4.8 seconds (12 seconds x 0.4) to 2.15 seconds (about 8.57 seconds x 0.25)." Calculations for the prior art specifications would yield that the length falls in the range of 4.0 seconds (10 seconds x 0.4) to 0.3 seconds (1.2 seconds x 0.25), wherein the claimed range partially (64%) falls within the calculated range of the prior art of record. Therefore, it would be obvious, if not inherent to use this particular time period range, based on the individual's needs and physical characteristics.

### ***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese whose telephone number is 571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR

March 18, 2005



Henry Bennett  
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Group 3700